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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/716,293

11/17/2003

Stephen P. Massia

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EXAMINER

NIEBAUER, RONALD T

ART UNIT

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1654

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/716,293	Applicant(s) MASSIA ET AL.	
	Examiner RONALD T. NIEBAUER	Art Unit 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 February 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 102, 105 and 106 is/are pending in the application.
- 4a) Of the above claim(s) 1 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 102, 105 and 106 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/24/09 has been entered.

Applicants amendments and arguments filed 12/3/08 are acknowledged and have been fully considered. Any rejection and/or objection not specifically addressed is herein withdrawn.

Election/Restrictions

The original restriction requirement was sent out 7/3/06. On 3/12/07 (as noted in the office action dated 1/7/08) applicants elected group I and the species of SEQ ID NO:124.

Applicant has amended claim 1 to cancel the reference to SEQ ID NO:124. As discussed in sections 706.07(h) and 819 of the MPEP applicant cannot switch inventions by way of an RCE.

As amended, claims 102,105-106 (which will be referred to as group 1) are drawn to bioconjugates comprising SEQ ID NO:124. Claim 1 (which will be referred to as group 2) is drawn to bioconjugates selected from a group that does not include SEQ ID NO:124.

Newly amended claim 1 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

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Inventions of group 1 and group 2 are directed to related products. The related inventions are distinct if: (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed have a materially different design since group 1 requires SEQ ID NO:124 while group 2 is drawn to other sequences. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 1 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

As discussed below the applicants elected species was found in the prior art. In accord with section 803.02 of the MPEP the claims to the elected species have been rejected.

Claims 2-101,103-104 have been cancelled.

Claims 102,105-106 are under consideration.

Priority

As noted in the previous rejection (see page 4 of 8/4/08 action) the instant application is a CIP of 10/295,734 (11/15/02).

MPEP section 601.05 states:

“If no ADS was originally filed, but applicant wants to submit an ADS to correct, modify,

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or augment the original application data, the ADS, even though it is the first-filed ADS, must be titled "Supplemental Application Data Sheet." See also 37 CFR 1.76(c)(1) and (2).

In the instant case, there was no originally filed ADS. On 12/2/08 applicants have filed an ADS. However, according to 37 CFR 1.76(c)(2) and MPEP section 601.05, the ADS submitted on 12/2/08 must be entitled "Supplemental Application Data Sheet". As such, the ADS submitted 12/2/08 is not proper so the previously supplied information (i.e. the instant application is a CIP of 10/295,734 (11/15/02)) will be relied upon.

Specification

The disclosure is objected to because of the following informalities:

37 CFR 1.821(d) states :

"Where the description or claims of a patent application discuss a sequence that is set forth in the "Sequence Listing " in accordance with paragraph (c) of this section, reference must be made to the sequence by use of the sequence identifier, preceded by "SEQ ID NO: " in the text of the description or claims, even if the sequence is also embedded in the text of the description or claims of the patent application."

In the instant case, sections 0119,0127 include sequences (those of SEQ ID NO:124) but no corresponding SEQ ID NO. It is noted that applicants made correction to section 0120 and 0126 on 11/19/07.

Appropriate correction is required.

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Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 102,105-106 are rejected under 35 U.S.C. 102(a) as being anticipated by Kalstad et al. (Proceedings of the Second Joint EMBS/BMES Conference Oct 23-26, 2002 as cited in IDS).

Kalstad teach (page 736 first column last paragraph) that the peptide CNAFKILVVITDGEK was conjugated with dextran. The peptide CNAFKILVVITDGEK is identical to SEQ ID NO:124 of the instant invention. As such, the peptide CNAFKILVVITDGEK conjugated with dextran meets the limitations of claims 102,105-106 of the instant invention.

It is noted that Kalstad et al. is 'by another' since the publication lists Kalstad and Panitch as two of the co-authors. It is noted that the instant application is a CIP of 10/295,734 (11/15/02). 10/295,734 does provide support for the elected species (SEQ ID NO:124) conjugated to dextran (page 17 last paragraph of 10/295,734; original claim 7), as well as support for hydrophilic polymers (page 9 past paragraph of 10/295,734) and polysaccharides (page 5 1st paragraph of 10/295,734). As discussed in the priority section the ADS submitted 12/2/08 is not proper so the previously supplied information (i.e. the instant application is a CIP of 10/295,734 (11/15/02)) will be relied upon.

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Response to Arguments 102a rejection

Since the claims have been amended, a new rejection adapted to the claims is recited above using the same reference as in the previous 102a rejection. Applicants arguments will be considered to the extent that they apply to the current rejection and claim set.

Applicants argue that an application data sheet was filed on December 2,2008 and thus Kalstad is not a proper reference.

Applicant's arguments filed 12/3/08 have been fully considered but they are not persuasive.

Although Applicants argue that an application data sheet was filed on December 2,2008, MPEP section 601.05 states:

“If no ADS was originally filed, but applicant wants to submit an ADS to correct, modify, or augment the original application data, the ADS, even though it is the first-filed ADS, must be titled “Supplemental Application Data Sheet.” See also 37 CFR 1.76(c)(1) and (2).

In the instant case, there was no originally filed ADS. On 12/2/08 applicants have filed an ADS. However, according to 37 CFR 1.76(c)(2) and MPEP section 601.05, the ADS submitted on 12/2/08 must be entitled “Supplemental Application Data Sheet”. As such, the ADS submitted 12/2/08 is not proper so the previously supplied information (i.e. the instant application is a CIP of 10/295,734 (11/15/02)) will be relied upon.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 102,105-106 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rieu et al (Journal Cell Biology 1994 v127 pages 2081-2091 as cited in IDS 11/10/04) and Laplantine et al (Journal of Cell Science 2000 v113 pages 1167-1176).

Rieu teach that the A-domain of beta2 integrin CR3 is a receptor for the hookworm-derived neutrophil adhesion inhibitor NIF (abstract). Rieu teach that integrins contain binding sites for protein ligands that play essential roles in leukocyte trafficking for example (abstract). Rieu map the NIF binding site to the A-domain and to specific peptide regions (abstract). Rieu teach (page 2086,2089) that particular A-domain peptides were immobilized and binding to RIF was tested. One of the peptides tested (A7 figure 6) corresponded to residues 232-245 and had the amino acid sequence NAFKILVVITDGEK. Rieu teach that the binding site comprised primarily peptide A7 (page 2089 first sentence of first complete paragraph, Figure 6).

Rieu does not expressly teach a peptide of SEQ ID NO:124

Rieu does teach that identification of the region in NIF mediating A-domain binding should be useful to understanding physiological functions (abstract). Rieu teach that the A-domain may be useful for treating hookworm infections (page 2090). Rieu also notes that certain peptides did not absorb adequately (page 2086 first paragraph last sentence). Thus one would be motivated to further study the A-domain NIF interaction.

Laplantine also teach about interactions between integrins and other proteins (title, abstract). Like Rieu, Laplantine recognize that integrins play an important role in triggering intracellular signaling (page 1167, page 1174). Laplantine investigate the interactions between a beta1 integrin and an alpha3 integrin (abstract). Laplantine specifically use surface plasmon resonance to investigate the interaction (page 1169 section 'surface Plasmon resonance, pages 1172-1173, Figure 7). Specifically, Laplantine teach that peptides corresponding to the beta1 subunit and containing an additional N-terminal cysteine residue were immobilized on a dextran through thiol coupling (page 1173 first column). The immobilized peptides were then exposed to peptides corresponding to alpha subunits and binding profiles were recorded (page 1173 first column).

Since Rieu teach investigating the interaction between an integrin and a possible interacting partner one would be motivated to use known techniques that are used to investigate such interactions. Since Rieu teach that identification of the region in NIF mediating A-domain binding should be useful to understanding physiological functions (abstract) and that the A-domain may be useful for treating hookworm infections (page 2090) and that certain peptides did not absorb adequately (page 2086 first paragraph last sentence) one would be motivated to

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further study the A-domain NIF interaction. Since Laplantine teach surface plasmon resonance as a specific method to investigate integrin interactions one would be motivated to use the method of Laplantine. Since Laplantine provide a specific example (see Figure 7) one would have a reasonable expectation of success.

Since Rieu teach that the binding site comprised primarily peptide A7 (i.e. NAFKILVVITDGEK) (page 2089 first sentence of first complete paragraph, Figure 6) one would be motivated to use such peptide as the sequence to attach to the dextran. Since Laplantine teach that the dextran is attached via thiol coupling to an additional N-terminal cysteine residue (page 1173 first column) one would be motivated to add an N-terminal cysteine to peptide A7 of Rieu to obtain CNAFKILVVITDGEK and then couple the dextran. The resulting product would be the peptide CNAFKILVVITDGEK (which is SEQ ID NO:124 of the instant invention) covalently attached by thiol coupling to a dextran thus meeting the limitations of claims 102,105-106 of the instant invention.

In the instant case, both Rieu and Laplantine are drawn to methods of identifying interacting regions between integrins and interaction partners. Rieu teach a method in which peptides were adsorbed to plastic wells but notes that numerous peptides did not absorb adequately (page 2086 first paragraph). Laplantine teach a method in which selected peptides containing an additional N-terminal cysteine were immobilized on dextran through thiol coupling and used as part of a surface plasmon resonance analysis. The claims would have been obvious because a particular known technique (i.e. surface plasmon resonance) was recognized as part of the ordinary capabilities of one skilled in the art. From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of

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success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

Related Prior Art

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

Arnaout WO 91/19511: Arnout teach SEQ ID NO:50 (comprises NAFKILVVITDGEK) (see claim 5 for example) and carriers for administering the peptides (claim 17).

Bocher et al (Journal of Immunological Methods 1997 v208 pages 191-202). Bocher teach the use of peptide-dextran conjugates compared to the use of peptide adsorbed onto immunoplates (abstract).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RONALD T. NIEBAUER whose telephone number is (571)270-3059. The examiner can normally be reached on Monday-Thursday, 7:30am-5:00pm, alt. Friday, EST.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Anish Gupta/
Primary Examiner, Art Unit 1654

/Ronald T Niebauer/
Examiner, Art Unit 1654